USAMRMC STRATEGIC COMMUNICATION PLAN

ARMED FORCES INSTITUTE OF REGENERATIVE MEDICINE (AFIRM)

MISSION

The Armed Forces Institute of Regenerative Medicine is dedicated to repairing battlefield injuries through the use of regenerative medicine technology.

BACKGROUND

Conventional weapons and the destructive force of improvised explosive devices ravage face, neck, head, and limbs, causing massive trauma and tissue loss. These injuries can take years to treat and often result in significant lifelong impairment. The field of regenerative medicine holds great potential for treating military personnel with these disfiguring and disabling injuries. Regenerative medicine employs a variety of techniques, often using the patient's own cells combined with degradable biomaterials and/or growth factors, to prompt the body to regenerate cells and tissues. The ultimate goal is to deliver advanced therapies capable of making our wounded warriors whole.

The AFIRM began in March 2008 when the USAMRMC, in partnership with the Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)), Office of Naval Research (ONR), the U.S. Air Force (USAF), the National Institutes of Health (NIH), and the Department of Veteran Affairs (VA), established the AFIRM to focus research centered on regenerative medicine for the treatment of battlefield injuries.

The AFIRM is a multi-institutional, interdisciplinary network of universities, military laboratories, and investigators under the framework of a cooperative agreement. The network is designed to promote a seamless integration of development, from basic

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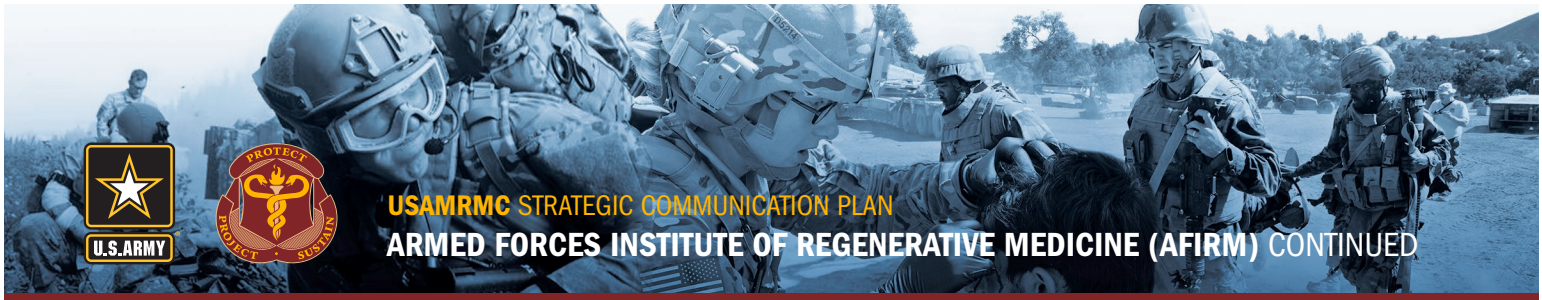

science research through translational and clinical research, as the best means of bringing regenerative medicine therapies to practice. The AFIRM has exceeded expectations by supporting 11 clinical trials and treating more than 200 patients with novel treatment strategies in wound repair and tissue replacement in the first 5 years.

The success of the first 5 years of the AFIRM led to a new cooperative agreement in 2013 awarded through an open and competitive solicitation. The areas of emphasis for research were adjusted to reflect the most pressing needs of our wounded warriors. The AFIRM II regeneration and repair research focus areas are skin, extremity, craniofacial, genitourinary, and vascularized composite tissue transplantation, such as hand and face transplants. The goal for the AFIRM II is to deliver capabilities that will transform the practice of medicine by finding innovative, regenerative medicine solutions to challenging clinical problems for both warfighters and the public at large.

The AFIRM cooperative agreements (the original AFIRM and AFIRM II) and awards under the Broad Agency Announcement (BAA), Small Business Innovative Research (SBIR), and other program announcements are managed by the AFIRM Project Management Office at the US Army Medical Materiel Development Activity (USAMMDA).

QUESTIONS & ANSWERS

Q *What is the Armed Forces Institute of Regenerative Medicine?*

A The Armed Forces Institute of Regenerative Medicine is dedicated to repairing battlefield injuries through the use of regenerative medicine. The AFIRM is managed and funded through USAMRMC, with additional funding from the OASD(HA), ONR, USAF, the NIH, the VA, and local public and private matching funding.

KEY THEMES AND MESSAGES

Overarching Theme: Delivering on the promise of regenerative medicine for our wounded warriors.

Overall aim: Making our warfighters whole by restoring form and function.

The DoD established AFIRM in 2008 with the mission of developing new products and therapies to treat severely injured warriors. AFIRM II was awarded in 2013 to continue regenerative medicine efforts for challenging military problems and to capitalize on advances from AFIRM I.

AFIRM has assembled a world-class group of engineers, scientists, and clinicians to make regenerative medicine a reality for our wounded warriors.

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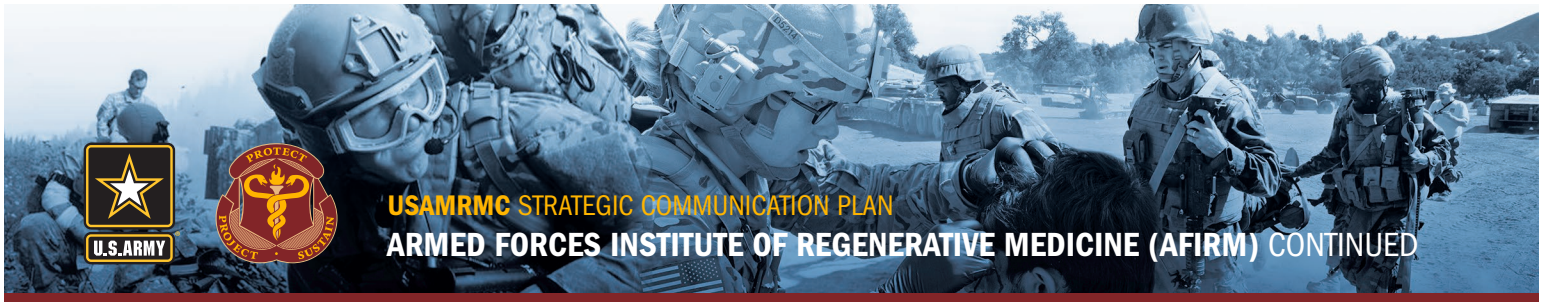

Q *Which institutions make up AFIRM?*

A AFIRM is a network of civilian research consortia coordinating and working with military institutions. In 2013, the consortium is led by Wake Forest University which manages a multi-institutional network of hospitals, academic laboratories, and industry partners.

Q *How much funding is allocated to AFIRM?*

A AFIRM II is a $75M five year effort, with a period of performance starting in 2013. The first 5 years of the AFIRM had over $300M in funding. The U.S. government (to include OASD(HA)) contributed $125M, the consortia brought in local public and private matching funds amounting to more than $80 million, $109M came from existing research areas.

Q *How were the AFIRM consortia chosen?*

A The cooperative agreements for AFIRM I and AFIRM II was a competitive solicitation process to a U.S. Army Program Announcement. The solicitation process for AFIRM II began in January 2010, with a Request for Information from USAMRMC. In 2011, a Program Announcement was released and over 12 consortia responded. The current awardee was selected in 2012 following a technical and programmatic review.

The solicitation process for AFIRM I began in January 2007, with a Request for Information from USAMRMC. Twenty-eight institutions responded. In April 2007, a draft Request for Proposal was sent to those 28 respondents for comment. In August 2007, a Program Announcement was released by the Army. Seven consortia responded. From those, two finalists were chosen for oral presentations to the Scientific Review Panel in December 2007. Ultimately, both finalists were deemed to have built excellent programs and both were recommended for funding.

Q *When does the AFIRM program start?*

A Research activity under the AFIRM is under way at the individual participating institutions.

KEY THEMES AND MESSAGES

(cont. from previous)

AFIRM addresses five areas: Burn Repair, Craniofacial Reconstruction, Extremity Repair, Genitourinary Repair, and Vascularized Composite Allotransplantation.

Regenerative medicine is cutting-edge medical technology for treating military personnel with debilitating, disabling, and disfiguring extremity injuries and burns.

The multi-institutional, interdisciplinary network of scientists and researchers are dedicated to accelerating the delivery of regenerative medicine to wounded warriors.

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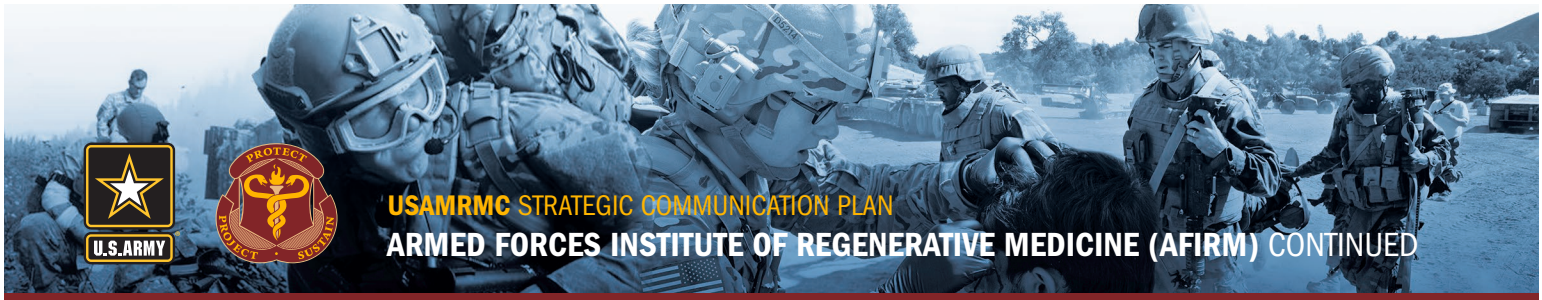

Q *What sort of therapies will be developed within AFIRM?*

A AFIRM was designed to speed the delivery of regenerative medicine therapies to treat the most critically injured service members. There are five major programs: **Burn Repair, Craniofacial Reconstruction, Extremity Repair, Genitourinary Repair, and Composite Vascular Allotransplantation.**

Q *Will AFIRM researchers use embryonic stem cells?*

A No. All of the research now funded through AFIRM will use adult-derived stem cells taken from the patient or from another consenting adult. Adult stem cells and progenitor cells are an integral part of normal wound healing and the formation of all new tissues. Many of the strategies being developed by AFIRM seek to improve wound healing and tissue repair by increasing the number or improving the function of adult stem cells. A patient's own cells or, in some cases, cells from another adult are used in conjunction with special drugs called bioactive factors, or with advanced biomaterials that serve as scaffolds for growth of new tissues.

Q *Can these stem cells regenerate entire arms and legs?*

A No, at least not yet. However, the use of these cells, bioactive factors and biomaterials can help injured service members to optimize their own capacity to heal and recover by forming new bone, skin, nerves, tendons, muscles, and blood vessels to replace damaged tissues. The AFIRM collaborators plan to use these new strategies to dramatically speed and enhance the outcome of tissue repair, leading to a more effective return to productive life after injury.

Q *What are tissue scaffolds?*

A Tissue scaffolds are the medical implants of the future: small, porous, tissue-like implants made of fully degradable, specially designed biomaterials that support cells at the site of injury and assist the body in growing new, functional tissue. When the damaged or lost tissue has been successfully replaced by new tissue, the scaffold will have been completely degraded and recycled by the body. Examples are regeneration of damaged or missing sections of bones, nerves, ligaments, blood vessels, and skin.

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Q *Are companies participating in AFIRM?*

A Dozens of commercial interests have expressed interest in working, and are working, with the AFIRM consortia as commercialization partners. The American medical device industry has taken a keen interest in speeding these important new therapies to market, not just for injured service members but for civilian patients as well. Commercial participation is encouraged and this participation, ultimately, will lead to better health care options for all Americans.

Q *How can other investigators participate in AFIRM?*

A The first contact should be with a member of the consortium. However, the USAMRMC has an open Broad Agency Announcement (BAA) intended to solicit extramural research and development ideas. The BAA is a competitive solicitation procedure issued under the provisions of the Competition in Contracting Act (CICA) of 1984 (Public Law 98-369). The BAA provides a general description of U.S Army Medical Research and Materiel Command's (USAMRMC's) research and development programs, including: research areas of interest; general information; evaluation and selection criteria; and proposal/application preparation instructions. Research funded through the BAA is intended and expected to benefit and inform both military and civilian medical practice and knowledge. Research proposal/applications are sought from national, international, for-profit, non-profit, public, and private organizations. The BAA is a continuously open announcement; pre-proposal/pre-applications and full proposal/full applications may be submitted at any time throughout the 12-month period. (See Federal Acquisition Regulations FAR 35.016). Program announcements also are published throughout the fiscal year to address specific topics in regenerative medicine.

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